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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,671	06/27/2003	Michael J. Pugia	017191.0033 (MSA-3452)	5201
28524 7590 10/15/2007 SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830			EXAMINER SINES, BRIAN J	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 10/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,671	PUGIA ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

Applicant's arguments with respect to the amended claims filed 8/1/2007 have been considered but are moot in view of the new ground(s) of rejection. The previous prior art rejections have been modified in view of the claim amendments and accompanying arguments. The applicant is reminded that in the submission of an RCE, applicant's are encouraged to file amendments at the time of filing of the RCE since after entry of the RCE and processing of fees, the application is immediately forwarded to the examiner for further examination. If additional time is needed, applicant should consider filing a suspension of action by the Office under 37 CFR 1.103(c) with the RCE (see MPEP § 706.07(h)). For more details on suspension of action, see MPEP § 709.

Oath/Declaration

The declaration under 37 C.F.R. section 1.132 filed 4/13/2007 has been reviewed by the examiner. The applicant's assertions are not persuasive. The accompanying black and white photographs, which are unlabeled, are of very poor quality and cannot be reviewed by the examiner accurately. In addition, the applicant's assertions are clearly not commensurate in scope to the claims. For example, the applicant's admit that both the *porous substrate pad* and the microfluidic posts must be present if liquid is to be distributed uniformly within the device. However, the instant claims do not positively recite a "porous substrate pad" within the claimed device. ("Many of appellant's arguments fail from the outset because, as the solicitor has pointed out, they are not based on limitations appearing in the claims."). See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982). Furthermore, the applicant's own assertions indicate that the

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incorporation of a porous substrate pad is a critical feature of the invention. A feature that is taught as critical in the specification should be recited in the claims (see MPEP § 2164.08c).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 6, 7, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 1, the specification is unclear with respect to the newly amended portion reciting that the array of posts are disposed to provide a lower capillary force in the well relative to the capillary force in the capillary passageway. The specification does not appear to specifically disclose this newly claimed feature pertaining to the capillary forces within the device. The specification does not provide sufficient detail, such as specific well, channel or spacing size dimensions, to provide this feature. The applicant's assert that this feature regarding the provisioning of this lower capillary force is not specifically taught in the specification (see page 2 of applicant's remarks).

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2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 6, 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 6, 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are:

Regarding claim 1, it is unclear as to what structural aspect of how the array of posts are disposed that enables a lower capillary force to be provided in the well relative to the capillary in the capillary passageway. For example, are the posts coated with a specific coating to enable this function? Is it the spacing distance between the posts themselves or the spacing distance between the posts and the sidewalls or surfaces of the interior of the well of the device? This claim feature is considered indefinite in that it is unclear as to what specific structure provides the difference capillary forces as claimed. Is there a specific size dimension that enables this function? The applicant's assert that this feature regarding the provisioning of this lower capillary force is not specifically taught in the specification (see page 2 of applicant's remarks). In claims drawn to an apparatus statutory class of invention, the structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device (see MPEP § 2172.01). Furthermore, a feature that is taught as critical in the specification should be recited in the claims (see MPEP § 2164.08c).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 4 and 6 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 4 – 6 and 8 of copending Application No. 10/608,400. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

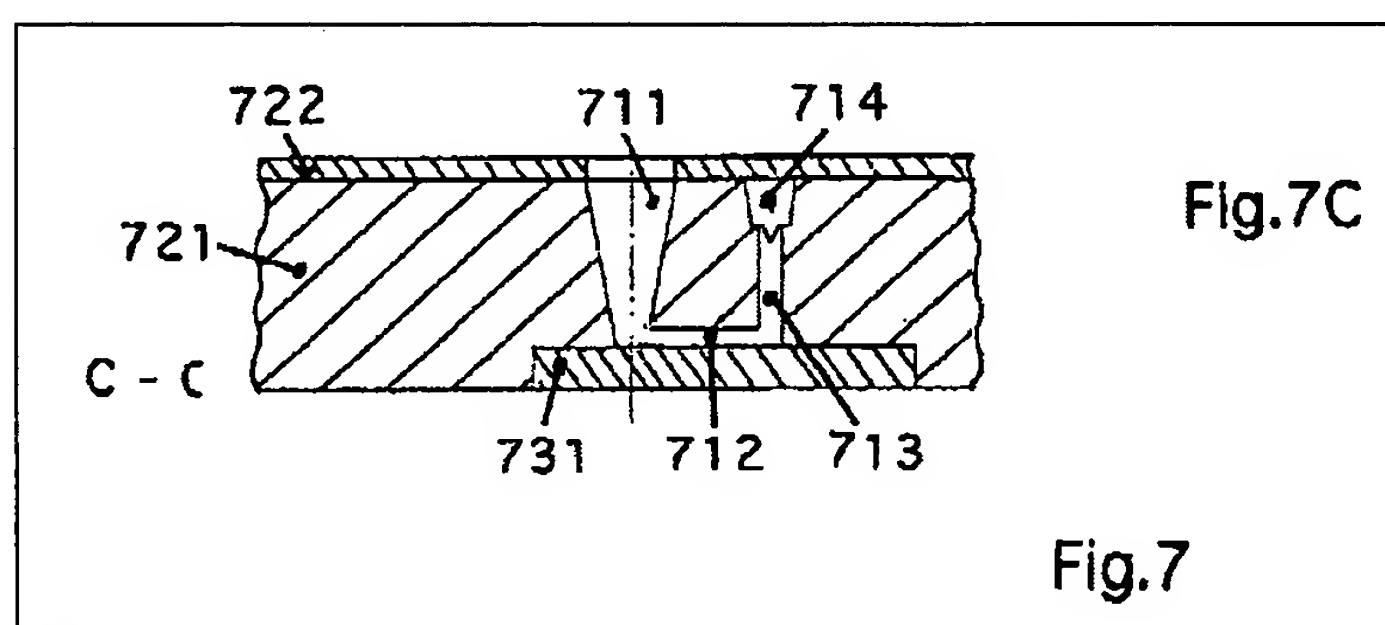
The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

2. Claim 7 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/608,400 in view of Wyzgol et al. (U.S. Pat. No. 6,776,965 B2) (hereinafter “Wyzgol”). This is a provisional obviousness-type double patenting rejection.

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Regarding claim 7, claim 1 of the copending application does not recite that the sample entry inlet port is tapered to engage the corresponding shape of a pipette for depositing a sample to be analyzed.

Wyzgol teaches a similar analytical microfluidic device comprising a tapered, funnel-shaped inlet port 711 designed for taking up the tip of a pipette for facilitating sample introduction into the device (see, e.g., col. 8, lines 30 – 37; figure 7 (7C)).

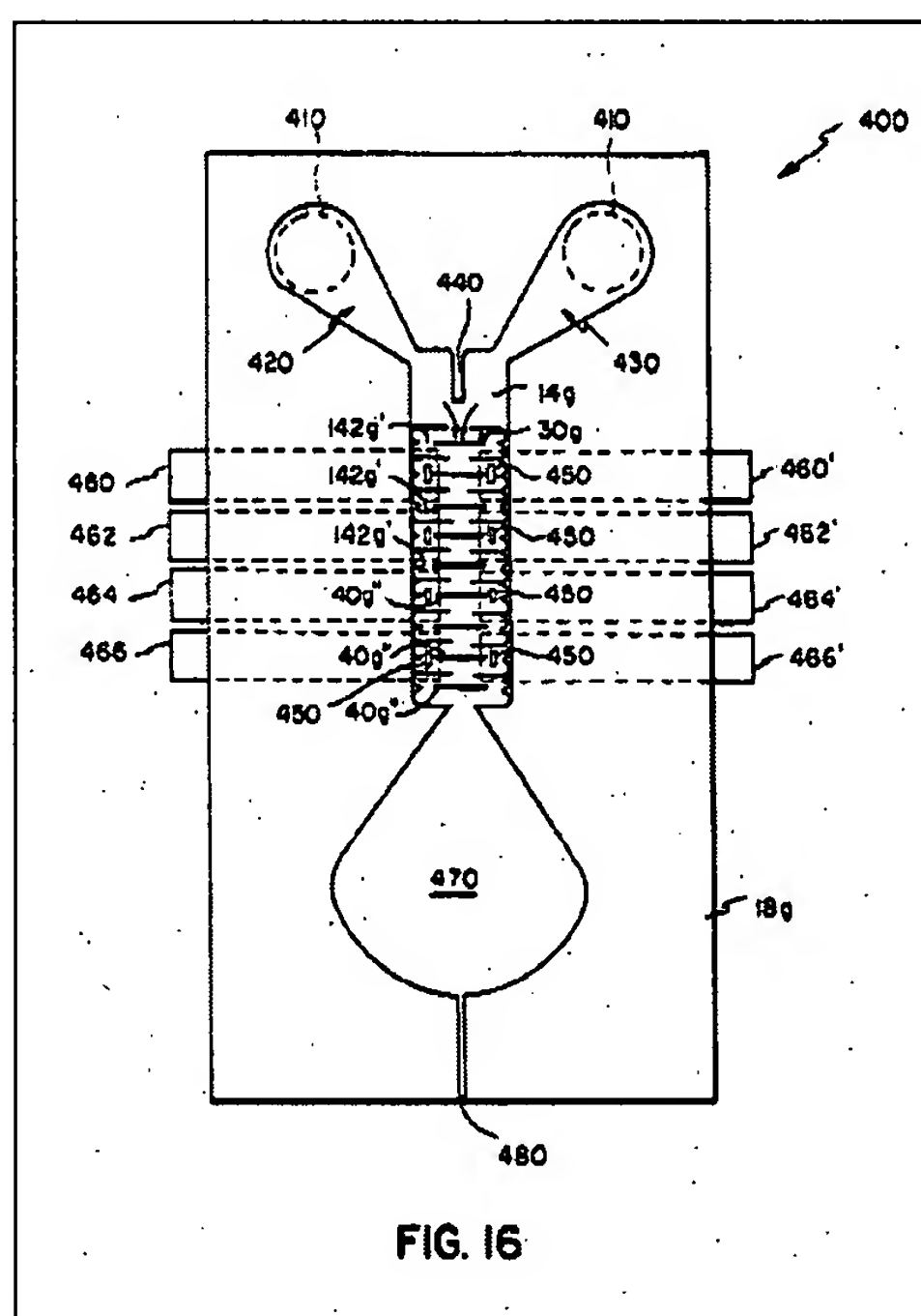


Hence, as shown by Wyzgol, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a tapered inlet port with an analytical microfluidic device for facilitating sample fluid introduction into the device for processing and analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a tapered inlet port as claimed with the disclosed microfluidic device.

3. Claims 9 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/608,400 in view of Columbus (U.S. Pat. No. 4,618,476) (hereinafter "Columbus '476"). This is a provisional obviousness-type double patenting rejection.

Regarding claim 9, claim 1 of the copending application does not recite the incorporation of an overflow chamber.

Columbus '476 teaches the incorporation of an overflow chamber 470 within a microfluidic device to facilitate effective sample fluid introduction and subsequent processing (see figure 16). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an overflow chamber within the disclosed microfluidic device to facilitate effective sample fluid introduction and subsequent processing.



Regarding claim 10, the recitation that the overflow chamber contains an indicator to detect the presence of excess sample is considered a statement of intended use, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the

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apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler (U.S. Pat. No. 6,113,855 A) in view of Columbus (U.S. Pat. No. 4,233,029).

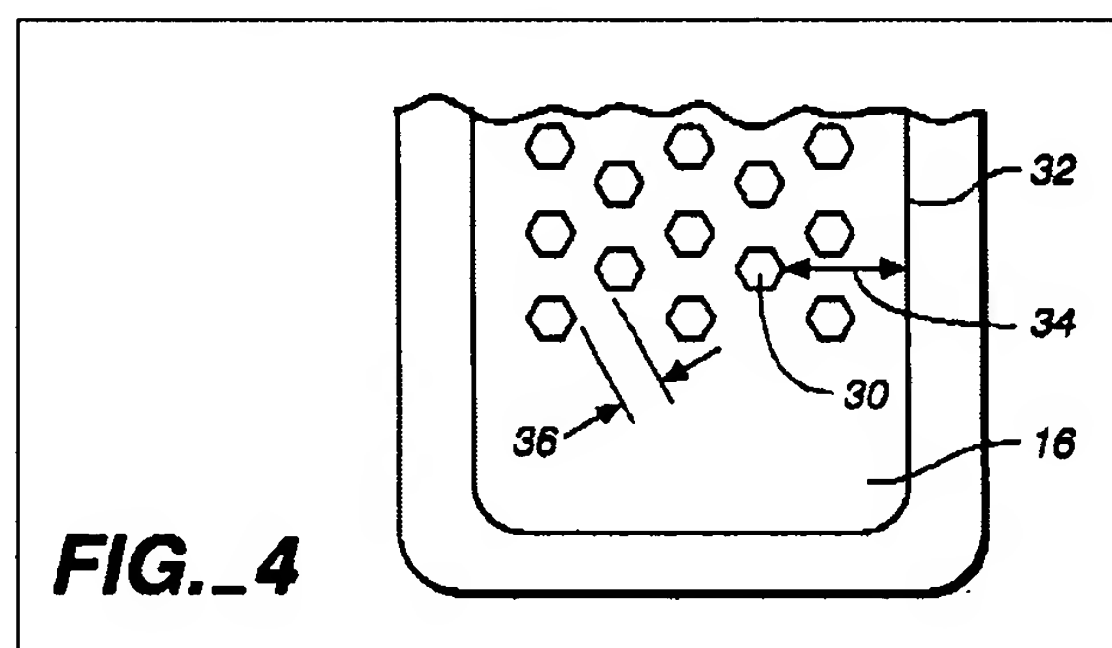
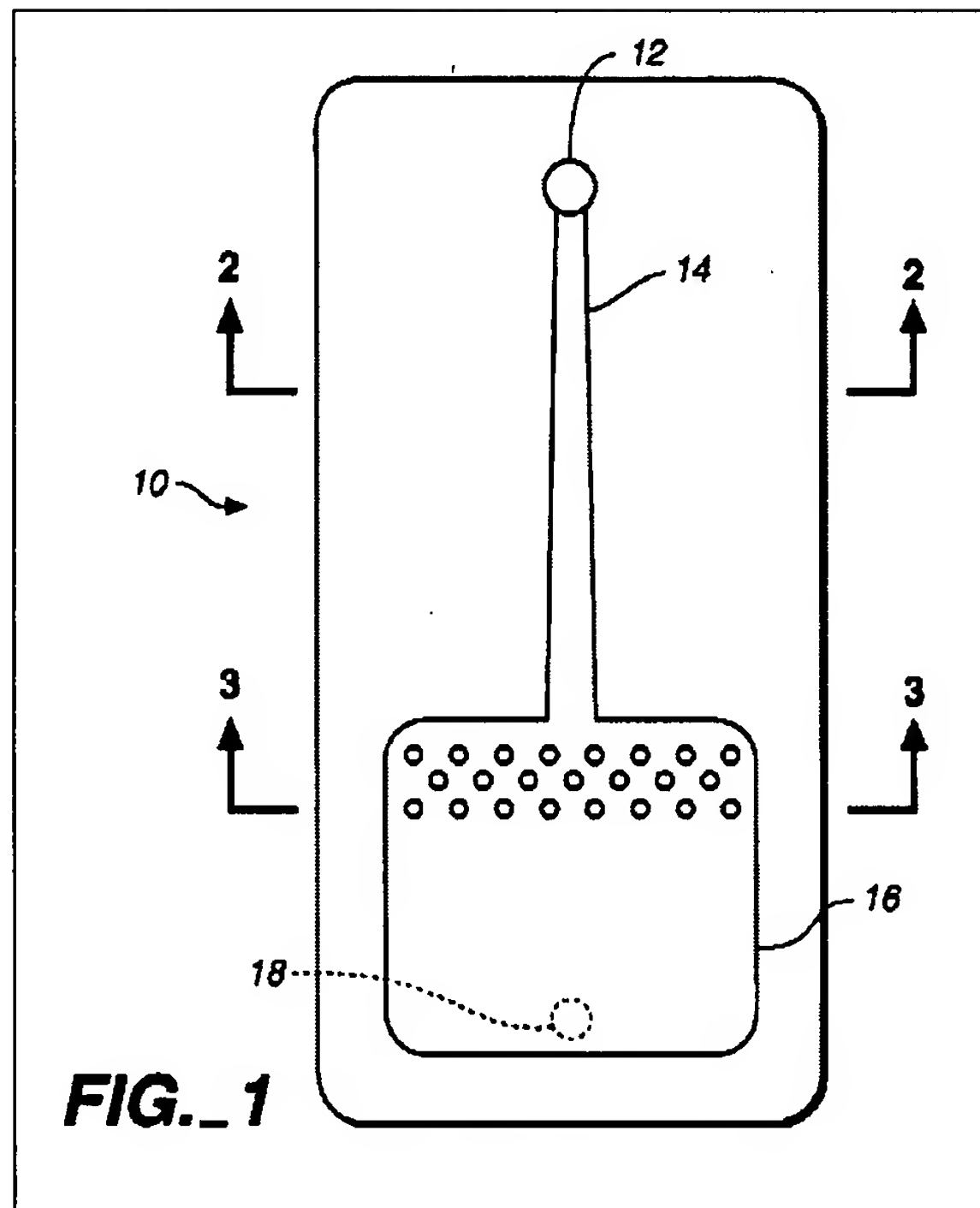
Regarding claim 1, Buechler teaches a microfluidic device comprising: an inlet port 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber (e.g., distal region 16) comprising an array of post structures (i.e., capillarity-

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inducing structures 30); and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4). As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the enclosed inlet chamber 16.

Buechler teaches that the inlet chamber 16 containing the assay volume comprises a reagent disposed on a substrate surface (e.g., surface bound reactants comprising solid-phase bound antibodies which react with sample antigen) (see, e.g., col. 4, lines 42 – 67; col. 5, line 54 – col. 6, line 5).

With respect to the newly added recitation that the array of posts are disposed to provide a lower capillary force in the chamber relative to the capillary force in the capillary passageway, since the claim does not provide any specific structure or size dimensions for the device, it is unclear as to how this feature defines over the prior art device structure.



Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber.

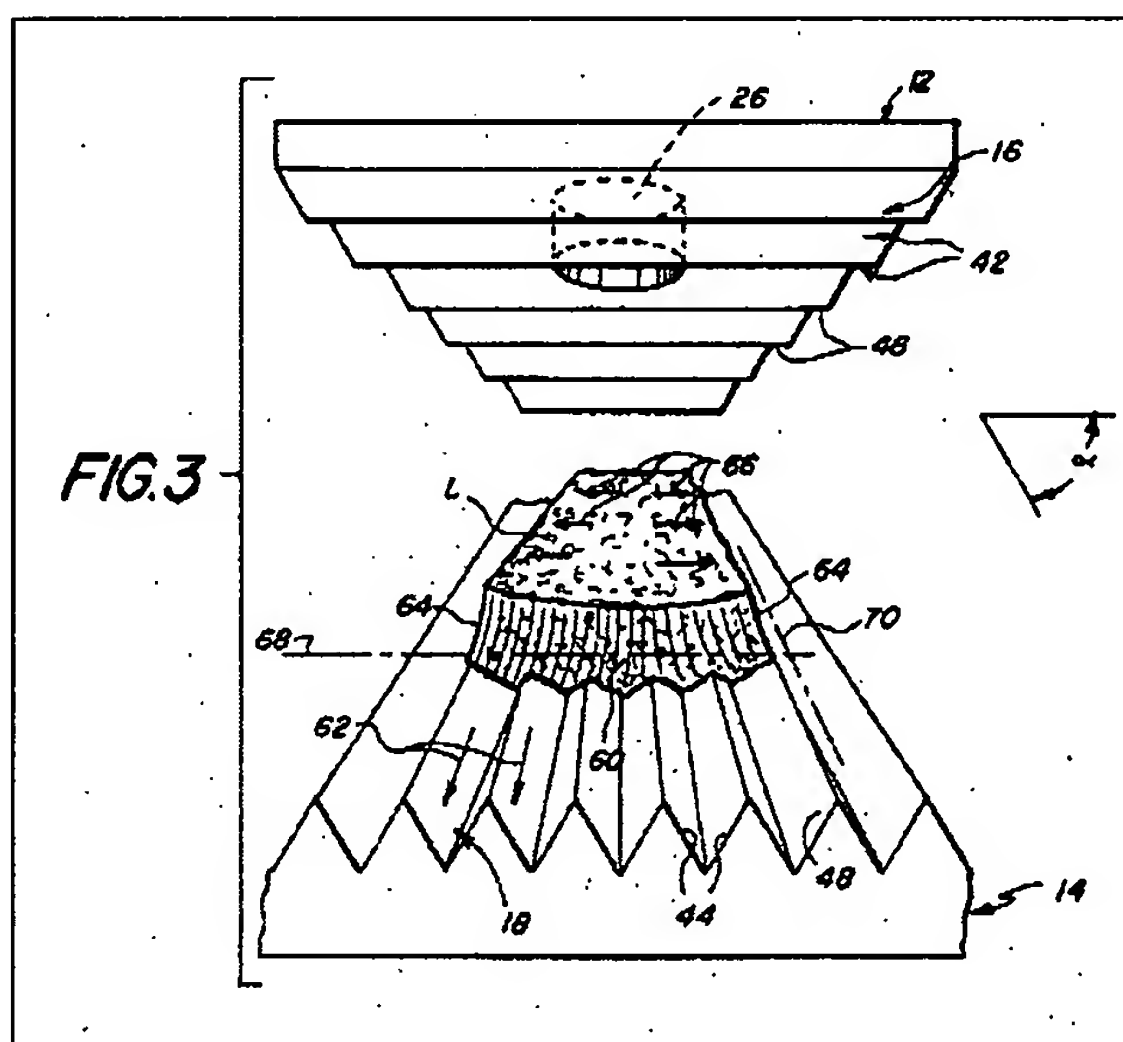
The applicant is advised that the Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a

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person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not.

(“The combination of familiar elements is likely to be obvious when it does no more than yield predictable results.”). See *KSR Int’l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007).

In this regard, Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3). Columbus shows an entry aperture 26 leading to chamber structure underneath defined by surfaces 16 and 18, wherein grooves 42 and 44 extend across the top surfaces of this chamber (see figure 3).



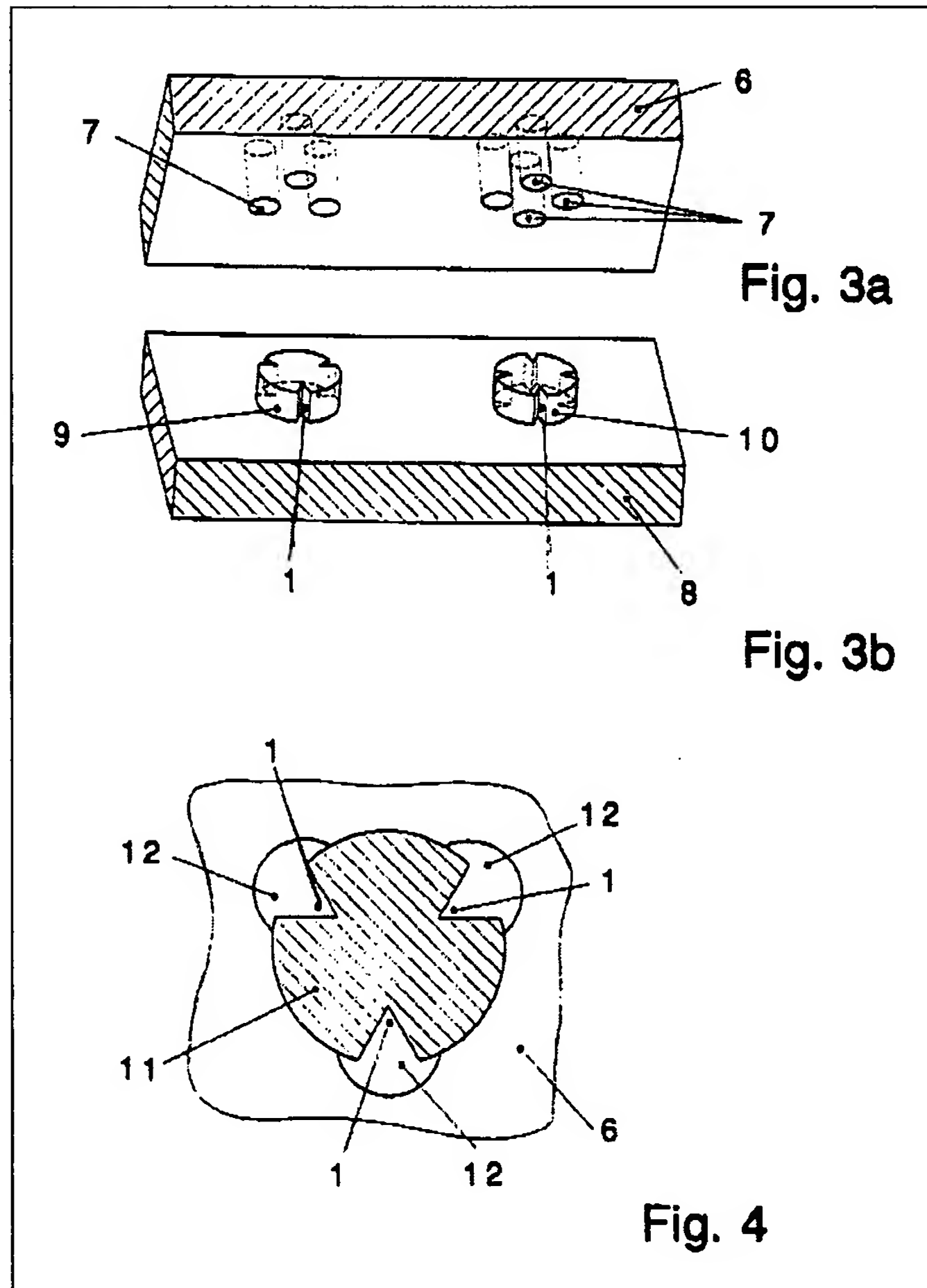
Hence, as shown by Columbus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with

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an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a familiar groove structure in the chamber as claimed with the disclosed microfluidic device for providing the predictable result of facilitating uniform sample fluid flow within the device.

2. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler and Columbus, and further in view of Peters (U.S. Pat. No. 6,296,126 B1).

Regarding claims 4 and 6, Buechler and Columbus are silent to the specific teaching of incorporating wedge-shaped cut-out structures with either a groove or weir structure configuration as claimed within the disclosed microfluidic device. As shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs 1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).



As evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability of incorporating the use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within a microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of

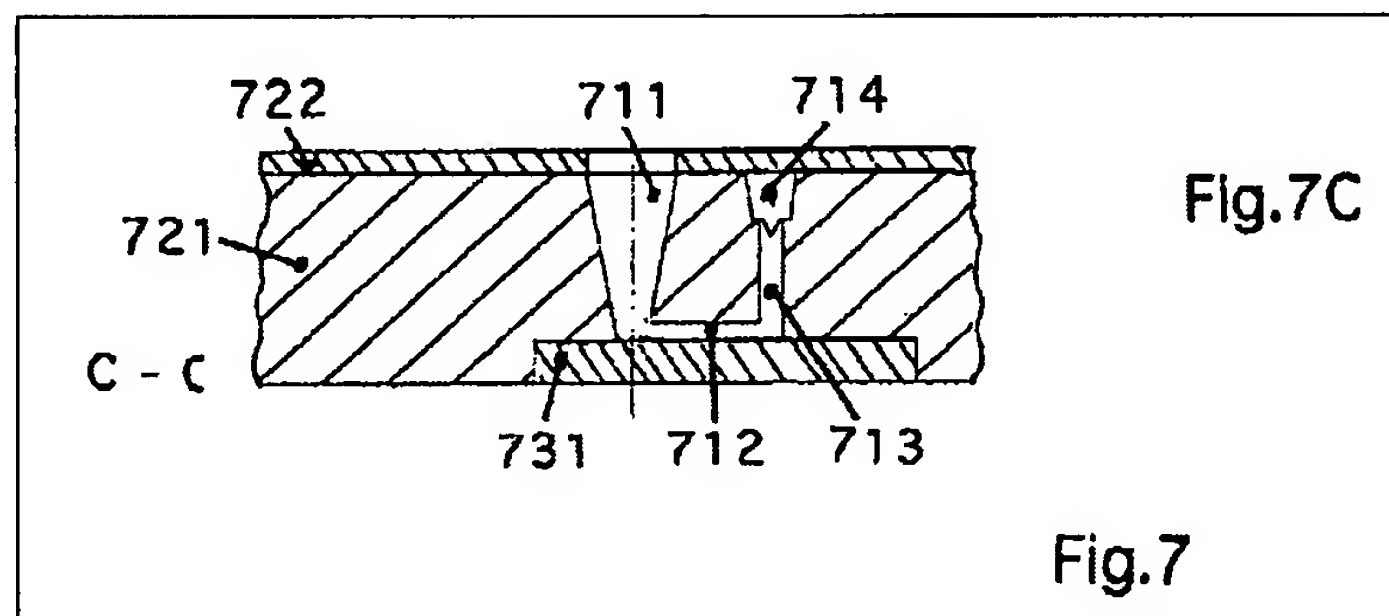
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wedge-shaped cut-out structures as claimed with the disclosed microfluidic device in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler and Columbus, and further in view of Wyzgol et al. (U.S. Pat. No. 6,776,965 B2) (hereinafter "Wyzgol").

Regarding claim 7, Buechler and Columbus do not specifically teach that the inlet port is tapered to engage the corresponding shape of a pipette for depositing a sample to be analyzed.

Wyzgol teaches a similar analytical microfluidic device comprising a tapered, funnel-shaped inlet port 711 designed for taking up the tip of a pipette for facilitating sample introduction into the device (see, e.g., col. 8, lines 30 – 37; figure 7 (7C)).



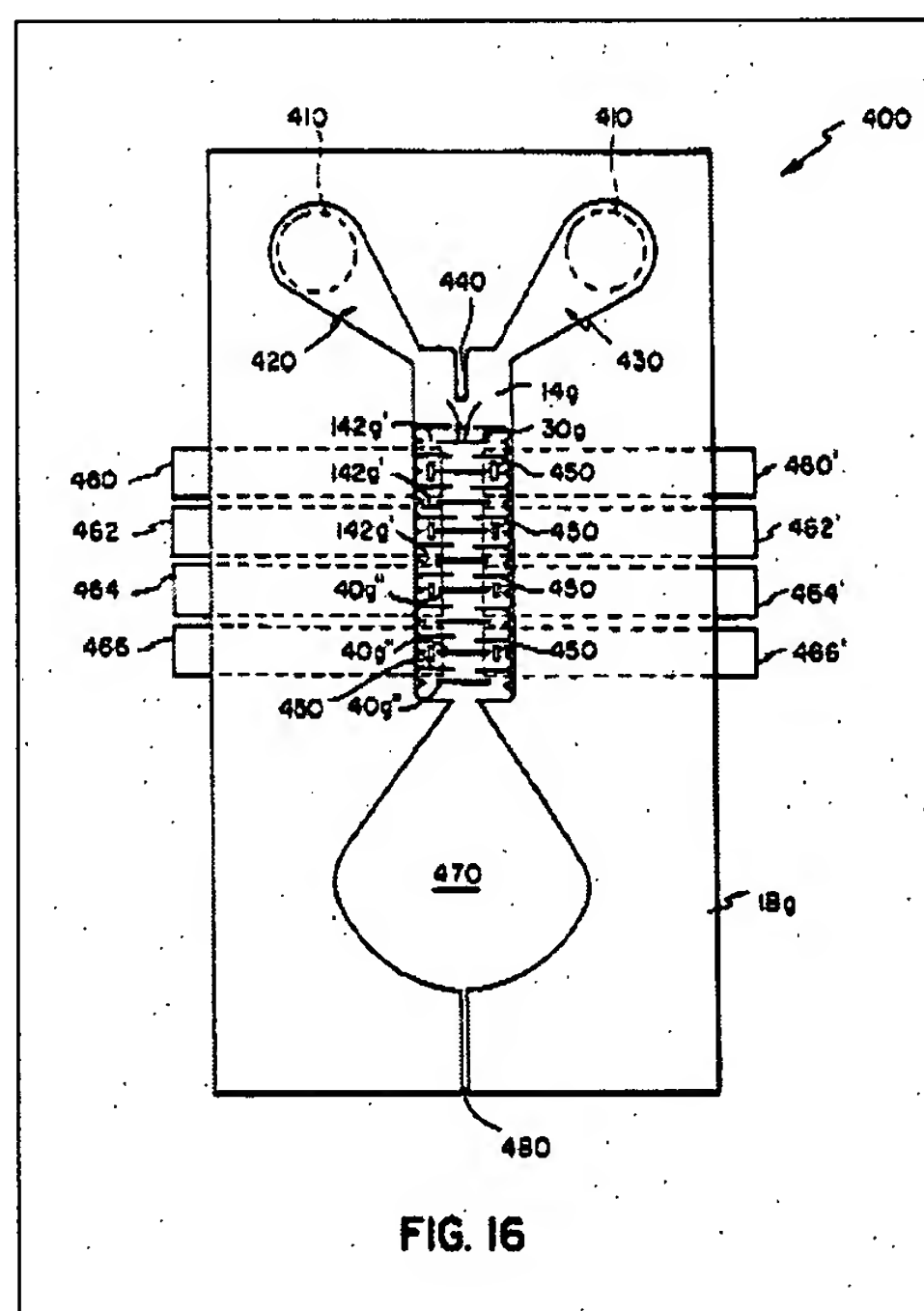
Hence, as shown by Wyzgol, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a tapered inlet port with an analytical microfluidic device for facilitating sample fluid introduction into the device for processing and analysis (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a tapered inlet port as claimed with the disclosed microfluidic device.

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4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuchler in view of Columbus (U.S. Pat. No. 4,618,476) (hereinafter "Columbus '476").

Regarding claim 9, Beuchler and Columbus do not specifically teach the incorporation of an overflow chamber.

Columbus '476 teaches the incorporation of an overflow chamber 470 within a microfluidic device to facilitate effective sample fluid introduction and subsequent processing (see figure 16). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an overflow chamber within the disclosed microfluidic device to facilitate effective sample fluid introduction and subsequent processing.



Regarding claim 10, the recitation that the overflow chamber contains an indicator to detect the presence of excess sample is considered a statement of intended use, which does not further delineate the structure of the claimed apparatus from that of the prior art. This claim

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recitation is not considered to further define the structure of the claimed apparatus itself. For example, this claim recitation does not specifically recite that the indicator is a part of the device itself, that is, the indicator is immobilized on a surface within the device. The indicator can be interpreted as being a liquid reagent within the device. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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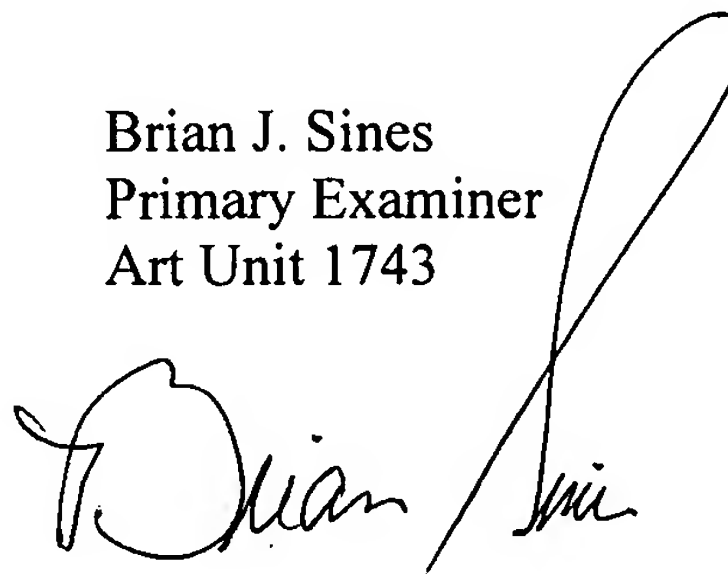
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian J. Sines
Primary Examiner
Art Unit 1743

A handwritten signature in black ink, appearing to read "Brian Sines", with a large, stylized loop at the end of the signature.